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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,677	05/15/2002	Nicole Suci-Foca	58332-A-PCT-US/JPW/FHB	2458

7590 10/11/2005

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EXAMINER

BELYAVSKIY, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/018,677	Applicant(s) SUCIU-FOCA ET AL.	
	Examiner Michail A. Belyavskiy	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-33, 37 and 39- 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34, 36 and 38 is/are rejected.
- 7) ☒ Claim(s) 35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/06/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 07/06/05 is acknowledged.

Claims 1-57 are pending.

2. Claims 1-33, 37 and 39- 57 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 34-36 and 38 read on a method of inducing anergic T helper cells comprising a step of incubating APC with allospecific T suppressor cells are under consideration in the instant application.

In view of the amendment, filed 07/06/05 , the following rejection and objection remains:

3 . The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 34, 36 and 38 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing anergic T helper cells which comprises overexpressing in the APC mRNA which encodes at least one monocytes inhibitory receptor (MIR) wherein said MIR is selected from the group consisting of ILT4 (MIR-10), ILT2 (MIR7) and ILT3 does not reasonably provide enablement for a method of inducing anergic T helper cells which comprises overexpressing in the APC mRNA which encodes at least *any* one of monocytes inhibitory receptor (MIR), as recited in claim 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons set forth in the previous Office Action, mailed 04/07/05.

Applicant's arguments, filed 07/06/05 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) applicant provided a representative number of MIR to enable the pending claims; (ii) nowhere is Papanikolaou et al., or Chang et al., teaches that ILT-3 or ILT-4 are the only MIR capable of generating a negative inhibitory signal.

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Contrary to Applicant's assertion, it is the Examiner position that Applicant does not provided a representative number of MIR to enable the pending claims. Applicant discloses that the invention is based on the results of micro-arrays assay that identify the specific genes which are differentially expressed in APC that have been exposed to allospecific Ts. Applicant disclosed that very specific MIR genes i.e. ILT4, ILT2 and ILT3 **were among the only 10-15 genes** that have been up-regulated (see page 118, lines 5-30 in particular). Applicant further disclosed that these molecules interact with MHC-class I molecules via Ig-like domains and regulate negatively the activation of APC, through recruiting an inhibitory signaling molecule , tyrosine phosphatase SHP-1 (see page 118, lines 25-30 in particular). Upregulation of the expression of said molecules is the essential mechanism in a method of inducing anergic T helper cells (see overlapping pages 118 and 119 in particular). In other words, Applicant disclosure teaches away from the genus of *any* MIR genes, that can be overexpressed in APC to induce anergic T helper cells because micro-arrays method explicitly indicates that only very specific genes have been differentially expressed in APC that have been exposed to allospecific Ts.

Applicant has not taught how overexpression of any MIR in APCs, other than the specific one as recited in claim 35, can be used in the method of inducing anergic T helper. Applicant has not provided sufficient biochemical information (e.g. structural characteristics, amino acid composition , physicochemical properties, etc) that distinctly identifies any MIR overexpression of which in APCs transmits negative inhibitory signals and can be used in the method of inducing anergic T helper cells, other than specific MIR encompassed by claim 35.

With regards to Applicants comments that nowhere is Papanikolaou et al., or Chang et al., teaches that ILT-3 or ILT-4 are the only MIR capable of generating a negative inhibitory signal.

Said references have been cited by the examiner to support the examiner position that in view of the fact that Applicant has not taught how overexpression of any MIR in APCs, other than the specific one as recited in claim 35, can be used in the method of inducing anergic T helper it is unpredictable which MIR, when overexpressed in APCs, would transmits negative inhibitory signals and thus can be used in the method of inducing anergic T helper cells.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed method of inducing anergic T helper cells which comprises overexpressing in the APC mRNA which encodes at least *any* one of monocytes inhibitory receptor (MIR), in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

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5. Claim 35 is objected to as being dependent upon a rejected base claim 34, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskiy, Ph.D.
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October 2, 2005


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